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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,124	06/08/2001	Edward T.H. Yeh	UTSH:249US	1154

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EXAMINER
BERTOGLIO, VALERIE E

ART UNIT	PAPER NUMBER
1632	7

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/878,124	Applicant(s) YEH ET AL.	
	Examiner Valerie E. Bertoglio	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-62 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 14-18, 28-37, 38 (a-e), 52(a-c and preamble), drawn to a method of screening for modulators of C-reactive protein by contacting an agent with C-reactive protein in vitro and assaying for ICAM, classified in class 530, subclass 350.

II. Claims 1-6, 14-18, 28-37, 38 (a-e), 52(a-c), drawn to a method of screening for modulators of C-reactive protein by contacting an agent with C-reactive protein in vitro and assaying for VCAM, classified in class 800, subclass 3.

III. Claims 1-6, 14-18, 28-37, 38 (a-e), 52(a-c and preamble), drawn to a method of screening for modulators of C-reactive protein by contacting an agent with C-reactive protein in vitro and assaying for E-selectin, classified in class 530, subclass 350.

IV. Claims 1,2, 6-10, 14-18, 28-37, 38 (a-e), 52(a-c and preamble), drawn to a method of screening for modulators of C-reactive protein by contacting an agent with C-reactive protein in vitro and assaying for MCP-1, classified in class 530, subclass 350.

V. Claims 1,2,6,11 14-18, 28-37, 38 (a-e), 52(a-c and preamble), drawn to a method of screening for modulators of C-reactive protein by contacting an

agent with C-reactive protein in vitro and assaying for iNOS-1, classified in class 530, subclass 350.

VI. Claims 1,2,4-7, 9-11, 14-18, 28-37, 38 (a-e), 52(a-c and preamble), drawn to a method of screening for modulators of C-reactive protein by contacting an agent with C-reactive protein in vitro and assaying for monocyte chemoattractant protein-1, classified in class 530, subclass 350.

VII. Claims 1,2,4-6,11,14-18, 28-37, 38 (a-e), 52(a-c and preamble), drawn to a method of screening for modulators of C-reactive protein by contacting an agent with C-reactive protein in vitro and assaying for P-selectin, classified in class 530, subclass 350.

VIII. Claims 1,2,4-11,14-18, 28-37, 38 (a-e), 52(a-c and preamble), drawn to a method of screening for modulators of C-reactive protein by contacting an agent with C-reactive protein in vitro and assaying for endothelin-1, classified in class 530, subclass 350.

IX. Claims 1,2,4-6,11,14-18, 28-37, 38 (a-e), 52(a-c and preamble), drawn to a method of screening for modulators of C-reactive protein by contacting an agent with C-reactive protein in vitro and assaying for endothelin-receptor, classified in class 530, subclass 350.

X. Claims 1,2,4-7,9-11,14-18, 28-37, 38 (a-e), 52(a-c and preamble), drawn to a method of screening for modulators of C-reactive protein by contacting an agent with C-reactive protein in vitro and assaying for IL-6, classified in class 530, subclass 350.

XI. Claims 1,2,4-6,11,14-18, 28-37, 38 (a-e), 52(a-c and preamble), drawn to a method of screening for modulators of C-reactive protein by contacting an agent with C-reactive protein in vitro and assaying for heme oxygenase-1, classified in class 530, subclass 350.

XII. Claims 19-23, drawn to a method of identifying an agent by contacting C-reactive protein comprising incubating a cell in C-reactive protein, classified in class 530, subclass 350.

XIII. Claims 24-27, drawn to a method of identifying an agent by contacting C-reactive protein comprising incubating a cell that is in an animal in C-reactive protein, classified in class 530, subclass 350.

XIV. Claims 38 (f and preamble) and 39-49, drawn to a method of treating using a C-reactive protein modulator, classified in various classes and subclasses.

XV. Claims 50-51, drawn to a C-reactive protein modulator, classified in various classes and subclasses.

XVI. Claims 52(d), 53, 60, drawn to a method of modifying a protein, classified in various classes and subclasses

XVII. Claims 52(e-f), drawn to a method of assaying a modified protein for interaction with C-reactive protein, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

The methods of Groups I-XI are materially different and plurally independent from each other because each is practiced with materially different process steps and

technical considerations and requires materially distinct protocols and reagents. Each group is directed to assaying for expression of a materially and functionally distinct molecule.

Inventions I-XI and XII are patentably distinct because the method of Groups I-XI can be used to identify modulators of C-reactive protein in vitro while the methods of Group XII can be used to determine the effect of C-reactive protein on a cell. The methods of Groups I-XI and XII are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents.

Inventions I-XI and XIII are patentably distinct because the method of Groups I-XI can be used to identify modulators of C-reactive protein in vitro while the methods of Group XIII can be used to determine the effect of C-reactive protein on a cell in an animal. The methods of Groups I-XI and Group XIII are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents.

Inventions I-XI and XIV are patentably distinct because the method of Groups I-XI can be used to identify modulators of C-reactive protein in vitro while the methods of Group XIV can be used to treat inflammation. The purpose of Groups I-XI and Group XIV are different. The methods are not necessary for the treatment and the treatment is not necessary for the methods. The burden required to search Groups I-XI and Group XIV together would be undue.

Inventions I-XI and Invention XV are patentably distinct because, the method of Groups I-XI can be used to identify modulators of C-reactive protein in vitro while the agent of Group XV can be used to inhibit inflammation in vivo. The methods are not necessary to make the agent nor is the agent necessary for the methods. The burden required to search Groups I-XI and Group XV together would be undue.

The methods of each of Groups I-XI and Group XVI are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. Groups I-XI are directed to identifying a C-reactive protein modulator while the methods of Group XVI are directed to modifying a protein. The burden required to search Groups I-XI and Group XVI together would be undue.

The methods of Groups I-XI and Group XVII are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. Groups I-XI is directed to screening for modulators of C-reactive protein while Group XVII is directed to modifying C-reactive protein modulators and assaying the activity of the modified modulator. The burden required to search Groups I-XI and Group XVII together would be undue.

Invention XII and XIII are patentably distinct because, the methods of Group XII can be used as to screen for agents using a cell in vitro while the methods of Group XIII can be used to screen for agents in vivo. The protocols and reagents required for the

methods of Group XII and XIII are materially distinct and separate and are not dependent upon one another.

Inventions XII and XIV are patentably distinct because the method of Group XII can be used to identify modulators of C-reactive protein while the methods of Group XIV can be used to treat inflammation. The methods of Groups XII and XIV are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents.

Inventions XII and Invention XV are patentably distinct because, the method of Groups XII can be used to identify modulators of C-reactive protein while the agent of Group XV can be used to inhibit inflammation in vivo. The methods are not necessary to make the agent nor is the agent necessary for the methods. The burden required to search Groups XII and XV together would be undue.

The methods of each of Groups XII and Group XVI are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. Group XII directed to identifying a C-reactive protein modulator while the methods of Group XVI are directed to modifying a protein. The burden required to search Group XII and XVI together would be undue.

The methods of Groups XII and XVII are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and

reagents. Group XII is directed to screening for modulators of C-reactive protein while Group XVII is directed to modifying C-reactive protein modulators and assaying the activity of the modified modulator. The burden required to search Groups XII and XVII together would be undue.

Inventions XIII and XIV are patentably distinct because the method of Group XII can be used to identify modulators of C-reactive protein while the methods of Group XIV can be used to treat inflammation. The methods of Groups XIII and XIV are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents.

Inventions XIII and Invention XV are patentably distinct because, the method of Group XIII can be used to identify modulators of C-reactive protein while the agent of Group XV can be used to inhibit inflammation in vivo. The methods are not necessary to make the agent nor is the agent necessary for the methods. The burden required to search Groups XIII and XV together would be undue.

The methods of each of Groups XIII and XVI are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. Group XIII directed to identifying a C-reactive protein modulator while the methods of Group XVI are directed to modifying a protein. The burden required to search Group XIII and XVI together would be undue.

The methods of Groups XIII and XVII are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. Group XIII is directed to screening for modulators of C-reactive protein while Group XVII is directed to modifying C-reactive protein modulators and assaying the activity of the modified modulator. The burden required to search Groups XIII and XVII together would be undue.

Inventions XIV and XV are patentably distinct because, the method of Group XIV can be used to treat inflammation while the agent of Group XV can be used to modulate C-reactive protein in vitro. The methods are not necessary for the modulator and the modulator is not necessary for the methods. The burden required to search Groups XIV and XV together would be undue.

The methods of each of Groups XIV and XVI are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. Group XIV is directed to treating inflammation in vivo while the methods of Group XVI are directed to modifying a protein. The burden required to search Groups XIV and XVI together would be undue.

The methods of Groups XIV and XVII are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. Group XIV is directed to treating inflammation in vivo while Group XVII is

directed to modifying C-reactive protein modulators and assaying the activity of the modified modulator. The burden required to search Groups XIV and XVII together would be undue.

Inventions XV and XVI are patentably distinct because, the agent of Group XV can be used to treat inflammation in vivo while the methods of Group XVI can be used to modulate a protein in vitro. The agent is not necessary for the methods and the methods are not necessary for the agent. The burden required to search Groups XV and XVI together would be undue.

Inventions XV and XVII are patentably distinct because, the agent of Group XV can be used to treat inflammation in vivo while the methods of Group XVII can be used to assay the activity of a modified modulator in vitro. The agent is not necessary for the methods and the methods are not necessary for the agent. The burden required to search Groups XV and XVII together would be undue.

Inventions XVI and XVII are patentably distinct because the methods of Group XVI can be used to modify protein while the methods of Group XVII can be used to assay the activity of a modified modulator. The methods of Groups XIV and XVII are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The burden required to search Groups XVI and XVII together would be undue.

A preliminary examination of this application reveals that claims 54-59, 61 and 62 include terminology that is so unclear that no meaningful interpretation can be made and are, therefore, unsearchable and have been removed from consideration.

The "modified nucleic acid" of claims 54 and 59 and dependent claims 55-58, 61 and 62 lacks antecedent basis and it is unclear as to what nucleic acid is being claimed. Claims 54-59, 61 and 62 depend from claim 52, which does not require or product a modified nucleic acid. As such, the claims are uninterpretable and cannot be evaluated under 35 USC § 102, 35 USC § 103, or 35 USC § 112 first paragraph.

If applicants elect from Groups I-XI, claim 38 will be examined for steps a-e and claim 52 will be examined for steps a-c. The phrase "of inhibiting C-reactive protein modulated inflammation" in the preamble and step f of claim 38 and steps d-f of claim 52 will not be considered.

If applicants elect Group XIV, claim 38 preamble and step f will be examined. Claim 38 steps a-e will not be considered.

If applicants elect Group XVI, claim 52 step d will be examined. Claim 52 steps a-c, e, and f will not be considered.

If applicants elect Group XVII, claim 52 steps e-f will be examined. Claim 52 steps a-d will not be considered.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Valarie Bertoglio
Patent Examiner

MICHAEL C. WILSON
PATENT EXAMINER